General

Guideline Title

Chronic hepatitis B infection.

Bibliographic Source(s)

Singapore Ministry of Health. Chronic hepatitis B infection. Singapore: Singapore Ministry of Health; 2011 Mar. 51 p. [70 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Singapore Ministry of Health. Chronic hepatitis B infection. Singapore: Singapore Ministry of Health; 2003 Mar. 30 p.

Recommendations

Major Recommendations

Definitions of the level of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) and the grades of recommendations (A, B, C, D, GPP) are defined at the end of the "Major Recommendations" field.

Epidemiology and Natural History

C - Patients with chronic hepatitis B virus (HBV) infection and who are hepatitis B e antigen (HBeAg) negative should be checked for presence of hepatitis B virus deoxyribonucleic acid (DNA) if their serum alanine aminotransferase is repeatedly or persistently above normal limits. (Grade C, Level 2+)

B - Patients with chronic hepatitis B virus infection who are above 40 years of age should be followed up closely if they are still HBeAg positive or have chronic HBe-negative hepatitis B. These patients should be actively evaluated for cirrhosis and be more readily considered for treatment of hepatitis B virus infection. Regular and frequent surveillance of hepatocellular carcinoma should be carried out in these patients. (Grade B, Level 2++)

Screening and Vaccination of Those at Risk

C - Hepatitis B vaccine should be given to protect children at birth or as soon as possible thereafter in regions where the prevalence of hepatitis B virus infection is high. Babies born to hepatitis B surface antigen (HBsAg)-positive mothers are at high risk of developing chronic infection. (Grade C, Level 2+)

D - Other high risk groups, including persons who come into contact with blood or blood products (e.g., laboratory staff, surgeons and dentists,

hospital personnel, drug abusers) and individuals requiring repeated transfusions of blood or blood products, should also be vaccinated for hepatitis B. (Grade D, Level 4)

D - The following individuals should be vaccinated for hepatitis B:

- Sexually active individuals, especially those with multiple partners
- Close family and sexual contacts of subjects with chronic hepatitis B virus infection
- Individuals infected with human immunodeficiency virus (HIV)
- Travellers to hepatitis B endemic areas

(Grade D, Level 4)

An approach to hepatitis B screening for vaccination is shown in the algorithm in Figure 2 (in the original guideline document).

Screening Prior to Hepatitis B Vaccination

D - The following groups of people should be screened prior to hepatitis B vaccination:

- Persons born in intermediate and high endemic areas (see Figure 1 in the original guideline document)
- Young adults
- Health care workers
- Pregnant women
- Contacts of subjects with chronic hepatitis B virus infection (family, household and sexual contacts)
- Persons with multiple sexual partners/ history of sexually transmitted diseases
- Individuals with chronically elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST)
- Individuals infected with hepatitis C virus or human immunodeficiency virus (HIV)
- Men who have sex with men
- Subjects with high risk behaviours (intravenous [IV] drug users, sex workers)
- Immunocompromised subjects (dialysis patients, HIV-infected patients)
- Immigrants
- Prisoners

(Grade D, Level 4)

D - The following blood tests should be done as part of serologic screening before hepatitis B vaccination:

- HBsAg
- Hepatitis B surface antibodies (anti-HBs)
- Anti-hepatitis B core (HBc)

(Grade D, Level 4)

D - Serological screening for hepatitis B surface antigen and antibody should be done within 6 months pre-vaccination for all except newborn babies. (Grade D, Level 4)

B - Based on the results of an individual's serological screening for HBs antigen and antibody, clinicians should then act according to the table below:

HBsAg	Anti-HBs	Interpretation	Action to Take
Non reactive	<10 IU/L	i. If an individual did not have hepatitis B vaccination before • Not immune to hepatitis B virus.	i. Administer hepatitis B vaccination
		ii. If an individual had hepatitis B vaccinations before either	ii. Offer a booster dose of hepatitis B vaccination and check anti-HBs within 3 months

HBsAg	Anti-HBs	Interpretation	Action to Take
		a. The antibody level has waned to less than 10 IU/L, but the individual is still immune to the hepatitis B virus. OR b. The individual did not develop immunity against hepatitis B virus after the primary course of hepatitis B vaccination. NB*	OR Give them another course (3 injections) of hepatitis B vaccination & recheck anti-HBs within 3 months (to discuss options with patient)
Non reactive	>10 IU/L	Immune to hepatitis B.	Immunisation is not required.
Reactive	<10 IU/L	Presence of hepatitis B virus infection.	Clinically assess the patient for liver disease. To repeat the HBsAg test 6 months later. If HBsAg positive 2 times, 6 months apart, chronic hepatitis B infection confirmed.

*Under rare circumstances, the emergence of hepatitis B surface mutant ('s' mutant) virus can be associated with the absence of HBsAg and a negative or low titre of anti-HBs antibody. (Grade B, Level 2++)

D - Babies born to HBsAg-positive mothers should be tested for seroconversion following the hepatitis B vaccination, preferably 3 months after completion of course. (Grade D, Level 4)

C - For children not born to HBsAg-positive mothers, as well as adults, three doses of hepatitis B vaccine should be given at months 0, 1 and 6. After the primary 3-dose vaccine series, check anti-HBs within 3 months after the booster dose at month 6. (Grade C, Level 2+)

If anti-HBs ≥10 IU/L, the individual has developed immunity against hepatitis B virus.

C - For individuals previously vaccinated for hepatitis B and with anti-HBs levels <10 IU/L, consider repeat booster of hepatitis B vaccination or give a second course of hepatitis B vaccination before rechecking the anti-HBs antibody titre. (Grade C, Level 2+)

C - For immunocompetent people:

- With low risk of acquiring hepatitis B *and*
- Who have completed their hepatitis B vaccination *and*
- Who had previously demonstrated immunity to hepatitis B virus after their vaccination, there is no need to check for immunity again or receive booster injections if their anti-HBs is <10 IU/L later on.

(Grade C, Level 2+)

D - Anti-HBc total should be checked if an otherwise immunocompetent individual fails to seroconvert after 2 courses of hepatitis B vaccinations.

1. HBsAg negative, anti-HBs <10 IU/L, anti-HBc positive
   These individuals may have hepatitis B virus infection with low viral load and an undetectable level of HBsAg. Those who are tested positive for antiâ€'HBc alone may be in the 'window' phase of acute hepatitis B infection or they may have chronic hepatitis B virus infection with low level viraemia. Refer them to gastroenterologists/hepatologists for further workup.

2. HBsAg negative, anti-HBs <10 IU/L, anti-HBc negative
   Consider repeat vaccination with pre-S vaccine or other 3rd generation vaccine, if available, especially if the individuals belong to the high-risk group. They should be advised against high risk behaviour, which may expose them to hepatitis B virus infections. (Grade D, Level 3)

GPP - Patients whose HBsAg is positive for the first time should be evaluated as they may be patients with undiagnosed chronic hepatitis B virus infection even if the clinical criteria may not have been met yet. The appropriate follow-up actions should then be taken:

1. History taking: Ask for symptoms of liver disease, family history of chronic hepatitis B virus infection, any recent travel or high risk activity.
2. Physical Examination: Examine the patients. Look for signs of liver disease, e.g., stigmata of chronic liver disease, ascites, jaundice, etc.

3. Investigation: Check blood for liver function test and alpha-fetoprotein level.

If either the physical examination or the blood test results are abnormal, refer to the gastroenterologist. Consider admitting the patient to the hospital through accident and emergency (A&E) or direct access, if acute hepatitis B infection is suspected. (GPP)

Management of Chronic Hepatitis B Virus Infection

D - The following advice should be given to patients with chronic hepatitis B virus infection:

- Ensure that their sexual partners are vaccinated
- No sharing of toothbrushes and razors
- Cover open wounds
- No donation of body parts
- Clean blood spills with bleach/detergents

Note: Hepatitis B virus transmission is not transmissible through:

- Sharing of utensils, food or kissing as part of social greetings
- Participating in all activities including contact sports
- Social interaction with others (e.g., in schools, day care centres)

(Grade D, Level 4)

D - Management of patients with chronic hepatitis B should be tailored according to the patients' clinical state of liver disease (compensated versus decompensated liver disease) as well as their virologic and biochemical (i.e., the liver function test, in particular the serum transaminase levels) status.

1. For patients with HBsAg positive >6 months and well–compensated liver disease, in association with:
    A. HBeAg–positive hepatitis B virus infection and:
        i. Alanine aminotransferase (ALT) < upper limit of normal (ULN): no pharmacotherapy needed. Monitor ALT at least 6 monthly and HBeAg at least 12 monthly.
        ii. ALT 1-2× ULN: monitor ALT 3 to 6 monthly and HBeAg 6 monthly. Refer to specialist if persistent evidence of early deterioration of liver function or age > 40. Consider liver biopsy and treatment if biopsy shows significant liver damage.
        iii. ALT > 2× ULN: repeat ALT and HBeAg within 1 to 3 months. Refer to specialist if persistent. Treat immediately upon evidence of hepatic decompensation.
    B. HBeAg–negative Hepatitis B virus infection and:
        i. ALT < ULN: Monitor ALT 3 months later. If still normal, monitor ALT every 6 to 12 monthly.
        ii. ALT 1-2× ULN: Monitor ALT 3 to 6 monthly. Refer to specialist if persistent, evidence of early deterioration of liver function or age >40. If HBV DNA is >2000 IU/ml, consider liver biopsy and treat if biopsy shows significant liver damage.
        iii. ALT > 2× ULN: repeat ALT within 1 to 3 months. Refer to specialist if persistent. If HBV DNA >2000 IU/ml, consider treatment if persistent.
2. For patients with decompensated hepatitis B virus–related cirrhosis: Refer to gastroenterologist or hepatologist for management.

(Grade D, Level 4)

GPP - Surveillance of patients with chronic hepatitis B should be carried out regularly. The required frequency of surveillance for an individual will depend on his/her risk profile, which should be determined before the start of the surveillance programme (see below):

A. Baseline assessment to stratify risk
    - Check serum ALT, AST, bilirubin, albumin, prothrombin time, alpha-fetoprotein, HBsAg, HBeAg, anti-HBe and hepatitis B virus DNA
    - Liver imaging
B. Periodic reassessment is necessary. Frequency of surveillance is dependent on patients' risk profile:
    i. Low-risk group: 6 monthly serum ALT and bilirubin assessment - if abnormal, hepatitis B virus DNA should be checked.
    ii. Medium-risk group: 4-6 monthly serum ALT and bilirubin assessment - if abnormal, hepatitis B virus DNA should be checked.
    iii. High-risk group: 2-4 monthly serum ALT, bilirubin assessment, hepatitis B virus DNA assessment, appropriate to each set of circumstances. If abnormal the specialist will have to decide on further appropriate management

(GPP)

GPP - Most patients in medium-risk group and all patients in high-risk group should be referred for management by a specialist. (GPP)

B - For patients who have average risk of developing hepatocellular carcinoma (HCC), six-monthly blood tests for alpha-fetoprotein level and annual ultrasonographic examination of the liver is recommended.

For patients with increased risk of HCC, such as patients with cirrhosis, frequency of blood tests and ultrasonographic examination can be increased. (Grade B, Level 2++)

GPP - Patients who have undergone treatment for hepatitis B within the last 6 months and developed serum ALT > ULN or patients who display evidence of hepatic decompensation should be referred to a specialist for further management immediately. (GPP)

B - Patients can be considered for alternative class of therapeutic agents after they fail to respond to one class of drug.

- Patients should be actively screened for contraindications for use of interferon-alpha before they are considered for treatment with interferon-alpha as an alternative therapeutic agent.
- Treatment with nucleoside/tide analogue indefinitely may be considered in patients who have persistently elevated serum ALT and evidence of active cirrhosis histologically when he/she has failed to respond to treatment with interferon-alpha previously.

These patients, however, should only be managed by specialists. (Grade B, Level 2++)

GPP - Patients with HIV or hepatitis C virus co-infection should be referred for management by specialists. (GPP)

GPP - Patients with chronic hepatitis B virus infection post-organ transplantation should be managed by specialists, even if the liver function test appears normal. (GPP)

C - Pregnant women with replicative hepatitis B virus infection should be monitored closely after the mid-trimester and immediately postpartum for acute exacerbation of chronic hepatitis B. (Grade C, Level 2+)

Definitions:

Levels of Evidence

Level	Type of Evidence
1++	High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g., case reports, case series
4	Expert opinion

Grades of Recommendation

Grade	Recommendation
A	At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall

Grade	Recommendation
	consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
GPP (good practice points)	Recommended best practice based on the clinical experience of the guideline development group

Clinical Algorithm(s)

An algorithm for hepatitis B screening and vaccination is provided in the original guideline document.

Scope

Disease/Condition(s)

Chronic hepatitis B virus infection

Guideline Category

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Infectious Diseases

Internal Medicine

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To improve primary prevention of chronic hepatitis B virus infection
- To guide the management of patients with chronic hepatitis B virus infection

Target Population

Patients at risk of and with chronic hepatitis B virus infection

Interventions and Practices Considered

Prevention/Screening/Assessment

1. Serological screening for hepatitis B surface antigen (HBsAg), HBs antibody (anti-HBs), and hepatitis B core antigen (HBc) before vaccination
2. Hepatitis B vaccination
3. Hepatitis B immunoglobulin prophylaxis
4. Laboratory testing: bilirubin, albumin, prothrombin time, alpha-fetoprotein, alanine transaminase (ALT), aspartate aminotransferase (AST), and hepatitis B deoxyribonucleic acid (DNA)
5. Liver imaging (ultrasound)
6. Patient history and physical examination

Management/Treatment

1. Patient education on daily living and prevention of transmission
2. Monitoring and surveillance of exacerbation of hepatitis B
3. Individualized treatment of chronic hepatitis B with interferon–alpha, thymosin alpha-1, lamivudine, telbivudine or adefovir
4. Management of treatment failure
5. Referral to gastroenterologist/hepatologist as indicated

Major Outcomes Considered

- Morbidity and mortality related to chronic hepatitis B infection
- Incidence of liver cancer and hepatitis B-related diseases

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Searches were run on PubMed (1966-2009); EMBASE (1947-2009), and the Cumulative Index to Nursing & Allied Health (CINAHL) database (1984-2009) for searching evidence related to chronic hepatitis B infection. Additionally both the Cochrane Library (2009, Issue 12) and Centre for Reviews and Dissemination databases (DARE, NHS EED and HTA) were searched for systematic reviews and cost effectiveness studies. The guideline developers also performed Internet search on websites of guidelines agencies and professional societies that published clinical practice guidelines and consensus evidence on the given condition. These include the search for the last five years of the existing clinical practice guidelines (2005-2009) from sources of overseas guidelines agencies and professional bodies, e.g., National Guideline Clearinghouse, National Health Service (NHS) National Library of Guidelines, the Guidelines International Network, Agency for Healthcare Research and Quality (AHRQ), Canadian Medical Association (CMA) Clinical Practice Guidelines, New Zealand Guidelines Group, Australia's Clinical Practice Guidelines Portal websites.

Inclusion/exclusion criteria were used specific to the clinical questions to be answered. In general, search filters were used to further focus the type of studies to randomised controlled trials and systematic reviews of randomised controlled trials. If there is a paucity of higher level evidence, lower level evidence may be considered.

All searches used keywords and MeSH headings or the controlled vocabulary specific to the databases for the condition specified.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Level	Type of Evidence
1++	High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g., case reports, case series
4	Expert opinion

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These guidelines have been produced by a committee made up of general practitioners, gastroenterologists, hepatologists, an infectious disease specialist, a nurse clinician as well as a patient representative appointed by the Ministry of Health. These guidelines were developed using the best available current evidence and expert opinion.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Grade	Recommendation
A	At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
GPP (good practice points)	Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

See Section 7 in the original guideline document for a discussion of cost-effectiveness issues.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate management of chronic hepatitis B infection
- The longâ€‘term efficacy of hepatitis B virus vaccination is confirmed. Hepatitis B surface antibodies (anti-HBs) remain above the critical threshold for protection in 70% to 90% of immunised children over 10 years. The benefits of hepatitis B vaccination at birth are well proven in various populations since the implementation of such programmes in various countries in the world. Recent evidence also demonstrated the benefits of catch up vaccination programme among older children and adolescents in country of high endemicity.

Potential Harms

Not stated

Contraindications

Contraindications

Hepatitis B vaccination is contraindicated for those who are allergic to the hepatitis B vaccine or its preservative.

Qualifying Statements

Qualifying Statements

- These guidelines are not intended to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.
- The contents of this publication are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not ensure a successful outcome in every case. These guidelines should neither be construed as including all proper methods of care, nor exclude other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient, in the light of the clinical data presented by the patient and the diagnostic and treatment options available.
- Evidence-based clinical practice guidelines are only as current as the evidence that supports them. Users must keep in mind that new evidence could supersede recommendations in these guidelines. The workgroup advises that these guidelines be scheduled for review in 3 years after publication, or if new evidence appears that requires substantive changes to the recommendations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Singapore Ministry of Health. Chronic hepatitis B infection. Singapore: Singapore Ministry of Health; 2011 Mar. 51 p. [70 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2003 Mar (revised 2011 Mar)

Guideline Developer(s)

Singapore Ministry of Health - National Government Agency [Non-U.S.]

Source(s) of Funding

Singapore Ministry of Health

Guideline Committee

Workgroup on Chronic Hepatitis B Infection

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Singapore Ministry of Health. Chronic hepatitis B infection. Singapore: Singapore Ministry of Health; 2003 Mar. 30 p.

Guideline Availability

Electronic copies: Available from the Singapore Ministry of Health Web site .

Availability of Companion Documents

The following are available:

- Chronic hepatitis B infection. Executive summary of recommendations. Singapore: Singapore Ministry of Health; 2011 Feb. 10 p. Electronic copies: Available in Portable Document Format (PDF) from the Singapore Ministry of Health Web site .
- Chronic hepatitis B infection clinical practice guidelines addendum. Singapore: Singapore Ministry of Health. 1 p. Electronic copies: Available in PDF from the Singapore Ministry of Health Web site .
- Various slide presentations and videos for hepatitis B vaccination, what to do after diagnosis, and treatment indications and options are available from the Singapore Ministry of Health Web site .

Self-assessment questions and clinical quality improvement parameters are also available in the original guideline document .

Patient Resources

The following is available:

- Your guide to understanding hepatitis B. Singapore: Singapore Ministry of Health; 2011. 12 p. Electronic copies: Available in Portable Document Format (PDF) from the Singapore MOH Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on November 28, 2003. This NGC summary was updated by ECRI Institute on March 15, 2013.

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